

Fig 1

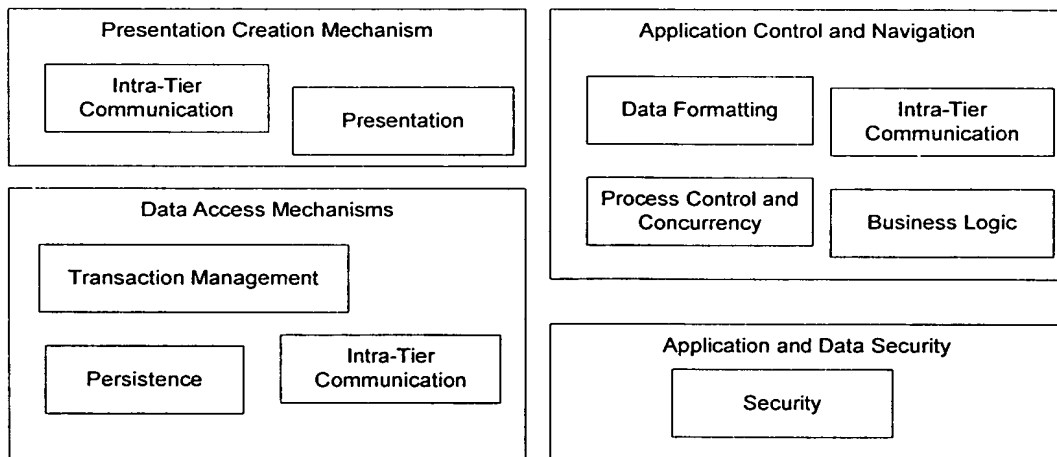


Fig 2

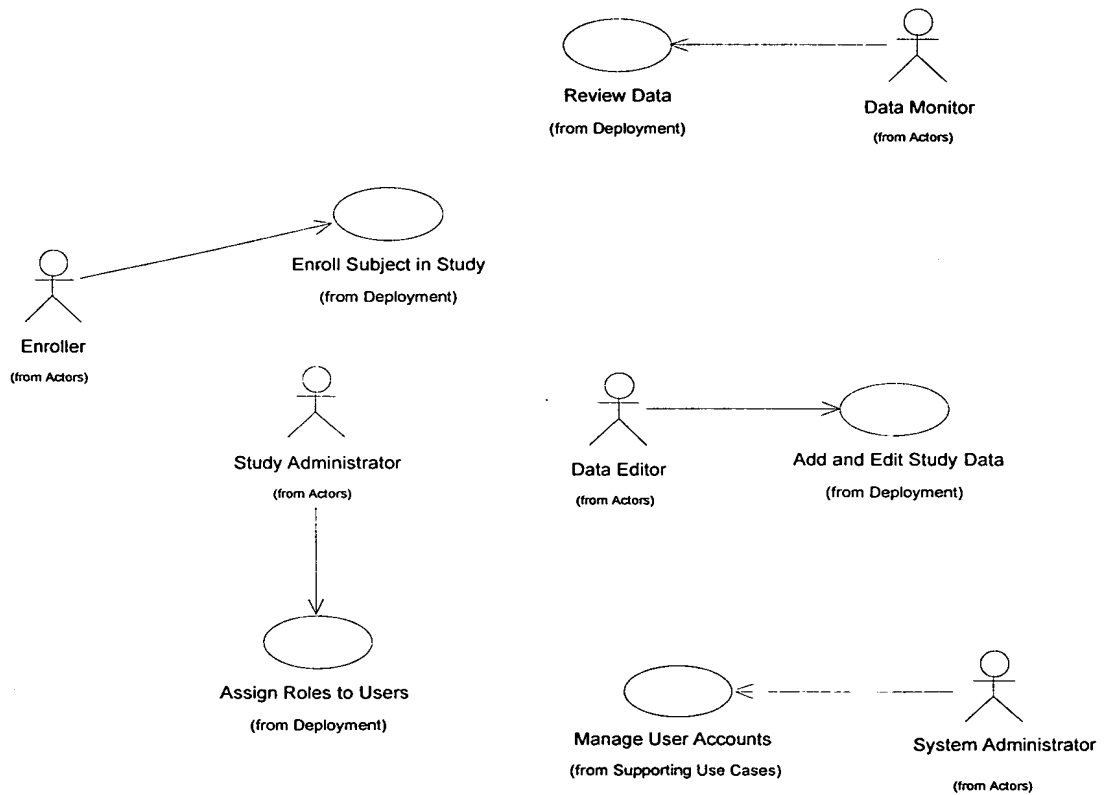


Fig 3

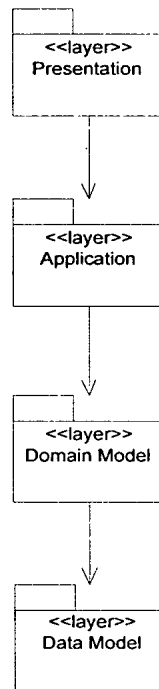


Fig 4

2025.05.01 10:56:50

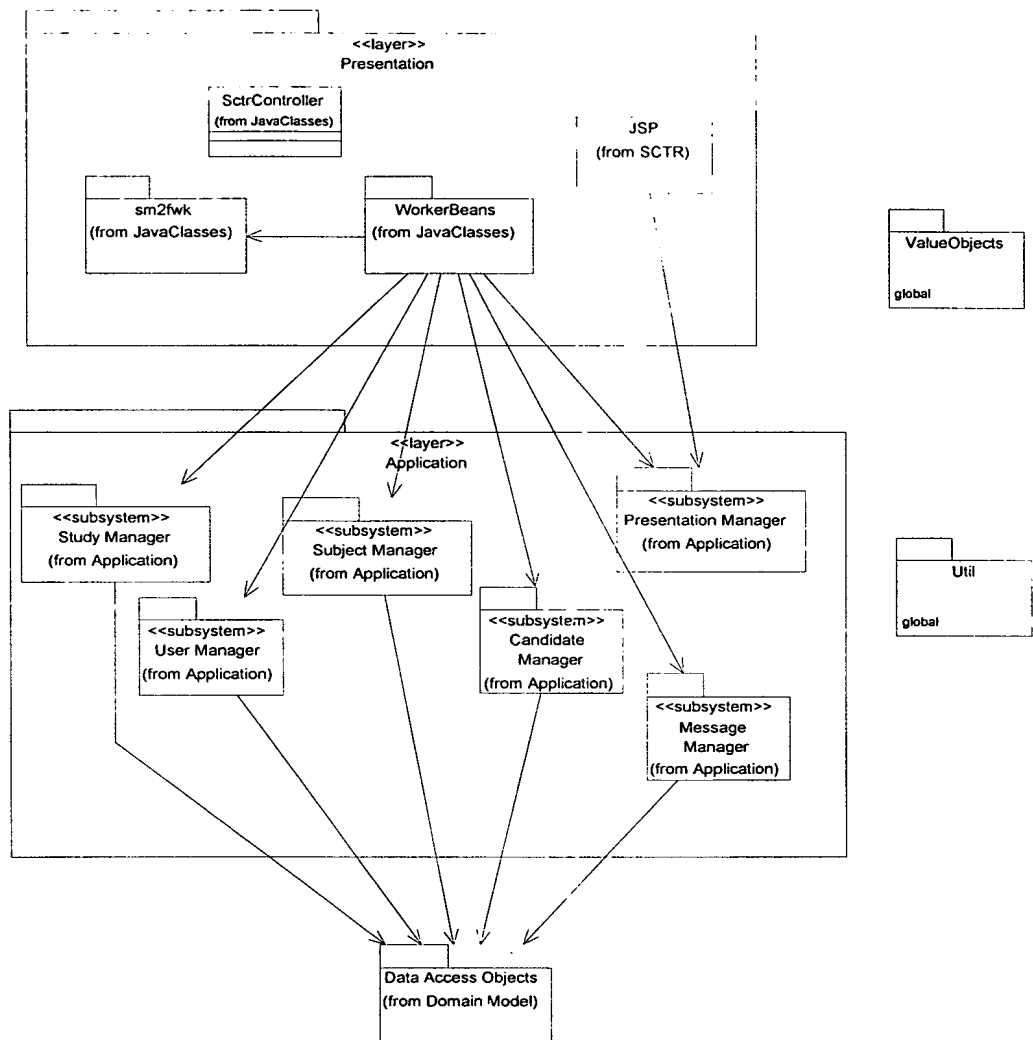


Fig 5

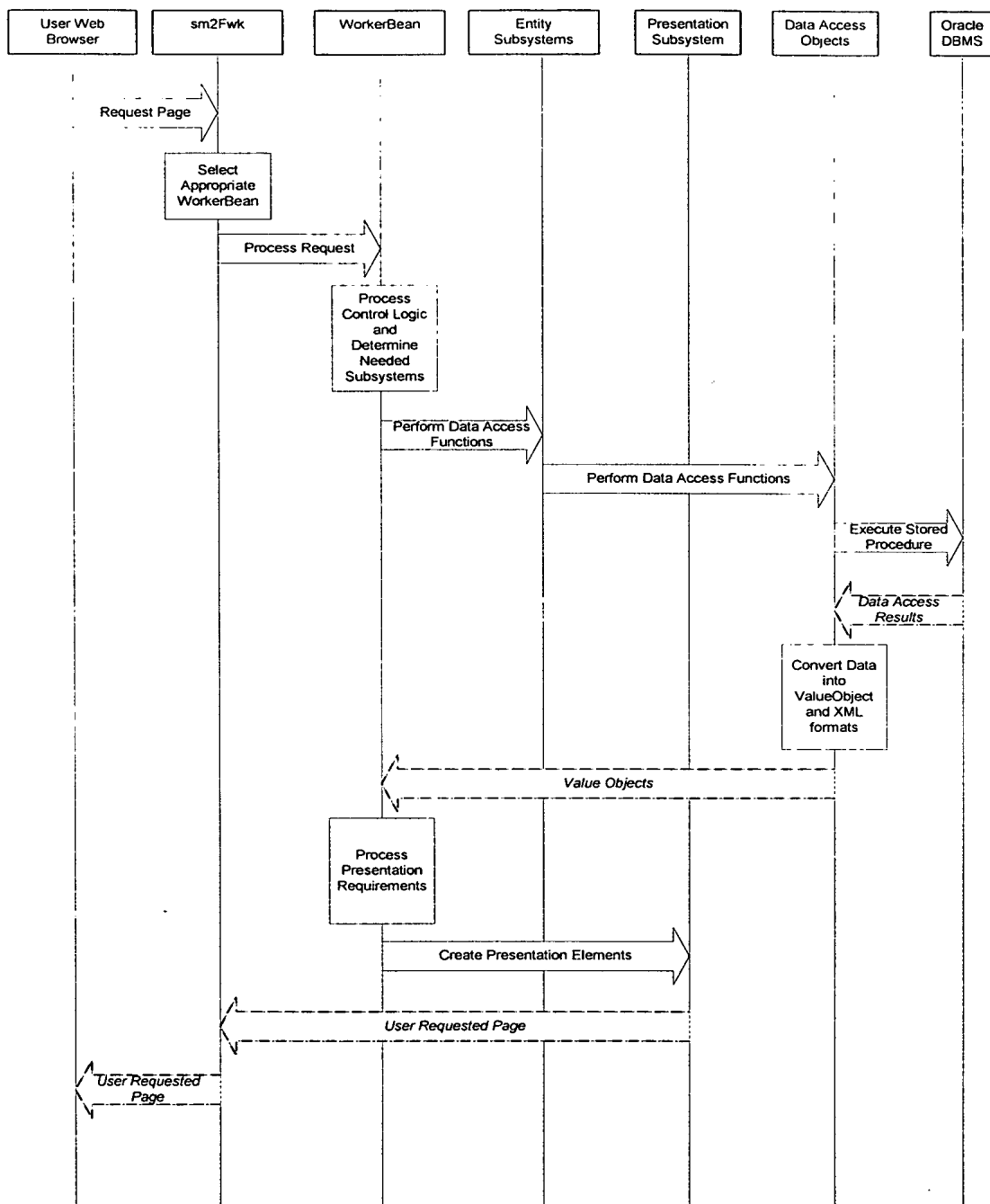


Fig 6

Login Function

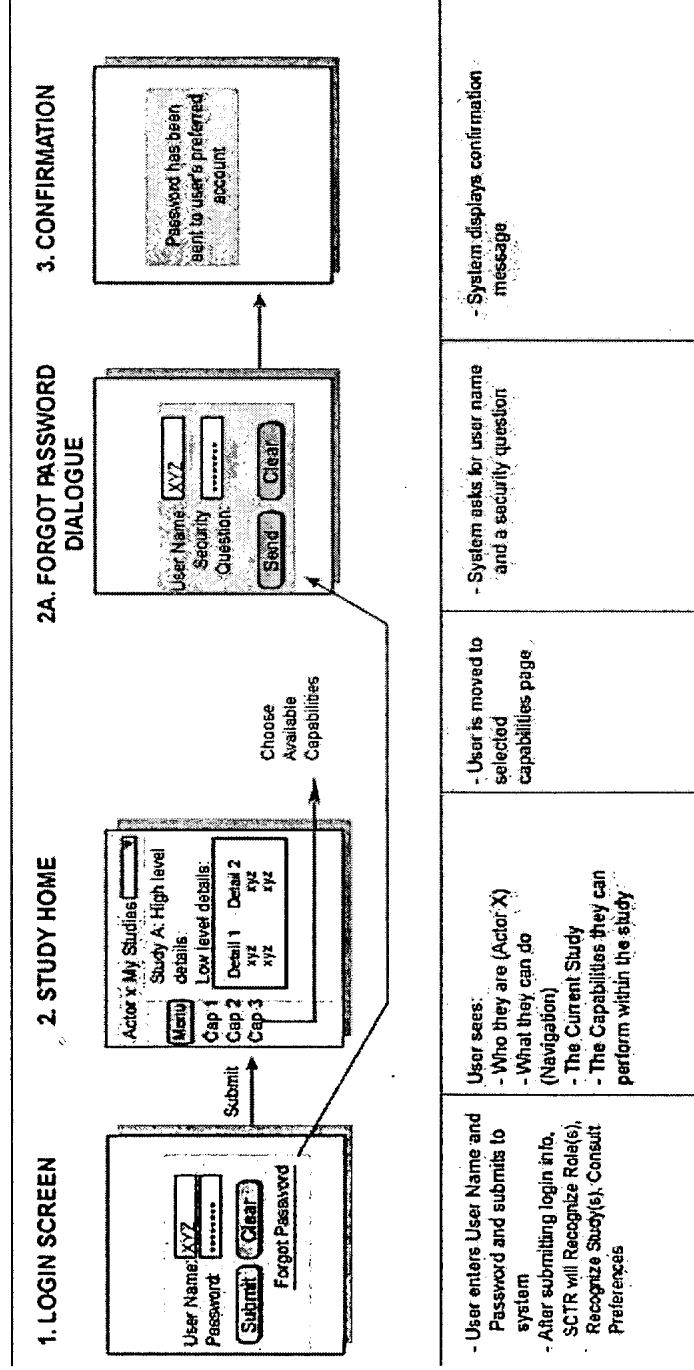


Fig 7

[Study Home](#) [Manage Subjects](#) [Reports](#) [Administration](#) [Register](#)

Study: 445599 Basal Joint Arthritis

Study Home

Change Studies

Summary ?

PI: Robert Hotchkiss, MD
Collaborators: 6
Enrolled Subjects: 133
Disenrolled Subjects: 10
Status: ACTIVE
Start Date: 09/24/2001
Last Modified: 09/25/2001

Study Alerts ?

08/12/2001 Subject 123442 Disenrolled from Study
07/23/2001 Collaborator Walter Reed Data Set Editability Suspended
06/18/2001 Enrollment for Basal Joint Arthritis closed
05/13/2001 Enrollment Opened For Fracture Callus Study
05/05/2001 Subject 234558 Enrolled into Basal Joint Arthritis Study

Reference Study Material

The files below represent background material for the study or points of information that may prove useful to the collaboration effort.

Author	Title	Collected	Modified	Action
Robert Hotchkiss, MD	NIH Grant Application	File Upload	10/01/2001	
Tim Wright, MD	IRB Submission	File Upload	10/01/2001	
Robert Hotchkiss, MD	IRB Consent Form	File Upload	10/01/2001	
Robert Hotchkiss, MD	Surgical Technique Movie	Generic URL	10/01/2001	

Append Reference Study Material

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SCTR Administrator
John Doe

Legal Notices

Fig 8

Register candidate Subject Function

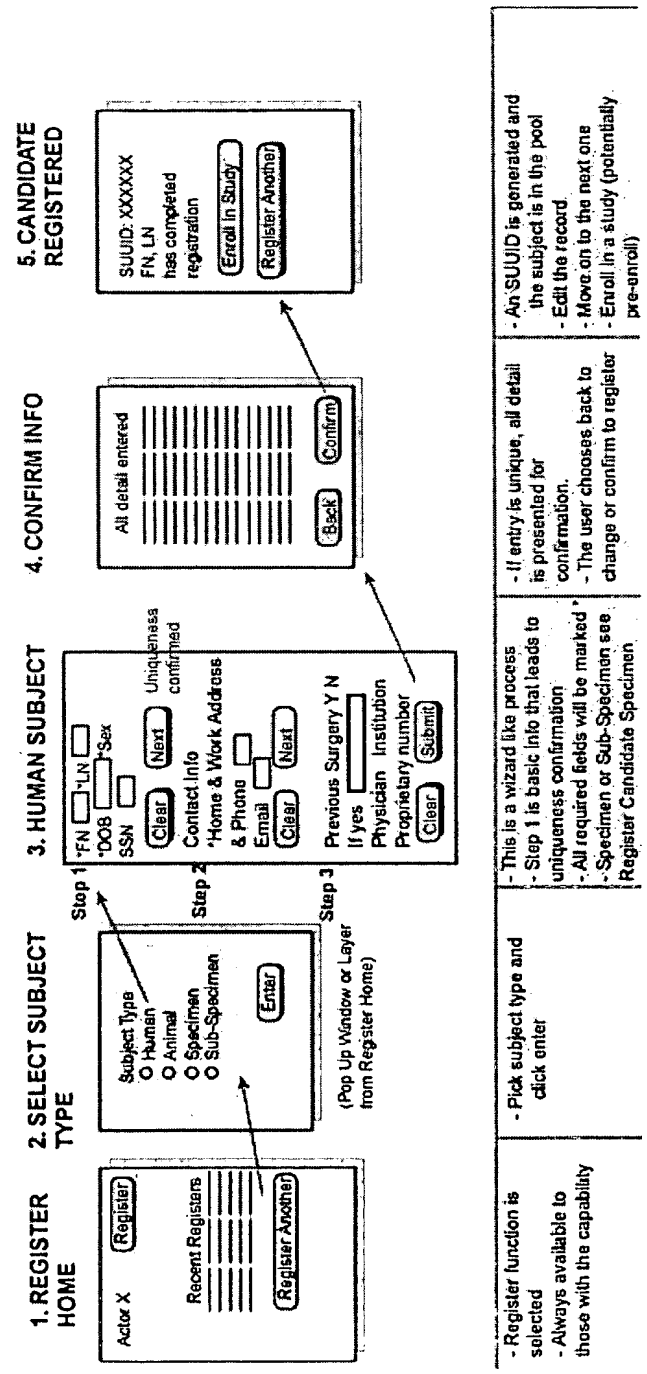


Fig 9

Register Specimen Function

1. REGISTER HOME 2. SELECT SUBJECT TYPE 3A. SPECIMEN DETAILS 4. CONFIRM INFO 5. SPECIMEN REGISTERED

Actor X

Recent Registers

Subject Type

☐ Human

☐ Animal

☐ Specimen

☐ Sub-Specimen

(Pop Up Window or Layer from Register Home)

Related to subject? y/n

*Institution

*Physical Location

*Received Date

Generation Date

*Weight

Search Subject Feature

3B. SUB-SPECIMEN FORM

Related to specimen? y/n

yield concentration

method of isolation

Search Specimen Feature

Sub ID: XXXXXX is registered

Connected to Sub ID: 123

<ul style="list-style-type: none"> - Register function is selected - Always available to those with the capability 	<ul style="list-style-type: none"> - Pick subject type and click enter 	<ul style="list-style-type: none"> - All required fields marked * - "Submit" sends the info for uniqueness checking - For additional sub-specimen fields look to Rose Domain Model - Cadaver entry fields include: body location, physical location, age, cause of death, patient history, paired/unpaired, dimensions 	<ul style="list-style-type: none"> - If an entry is determined unique, all detail is presented for confirmation. The user can go back to change or confirm to register 	<ul style="list-style-type: none"> - An Sub ID is generated and the specimen is in the pool - Ability to edit after acceptance is possible - Move on to the next one - Enroll specimen in a study - Sub-specimens are automatically enrolled as they must be connected to an enrolled specimen
--	---	--	---	---

Fig 10

ADVANCED SEARCH

Who I Am
Where I am

Search (Easy, Advanced)

Advanced Search

Keywords:

PATIENT:

SUUID:

Profile Created:

First Name:

Last Name:

Enrollment Date:

STUDY:

Study ID:

Condition:

Study Name:

Procedure:

Data sets:

Study Type:

Approval Date:

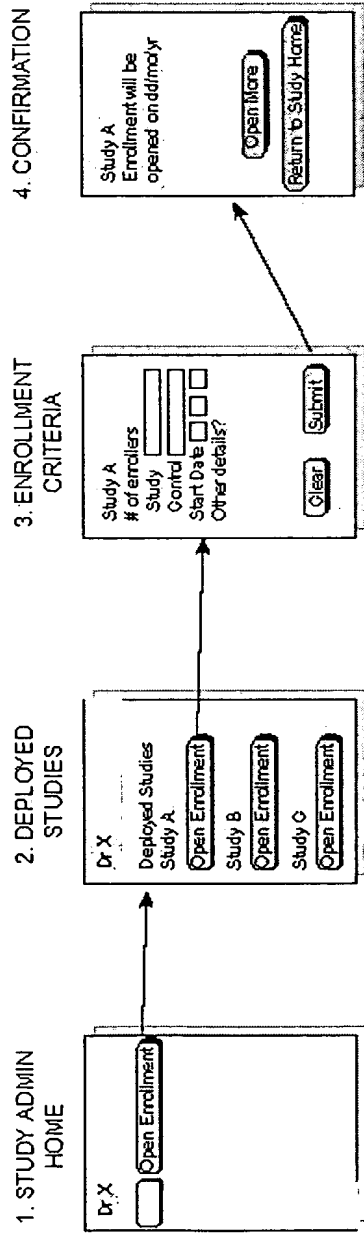
Start Date of Study:

Search

Clear

Fig 11

Open Enrollment Functions

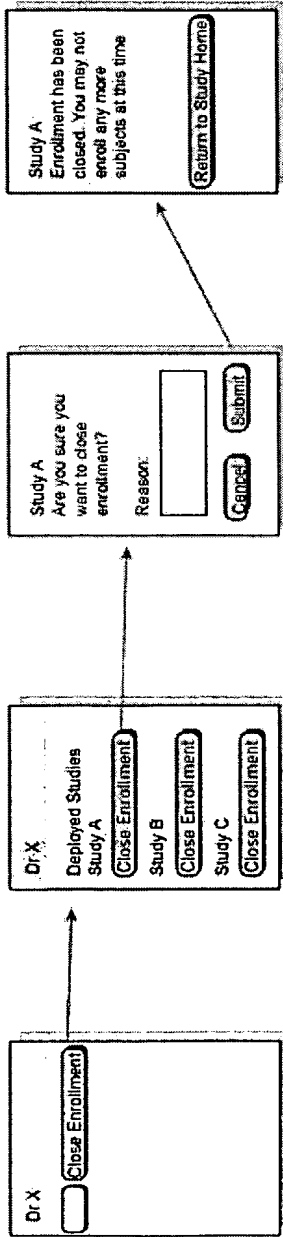


- User chooses open enrollment	- User selects study to open enrollment with	- User enters criteria and clicks submit	- Enrollment is opened - Enroller is notified
--------------------------------	--	--	--

Fig 12

Close Enrolment Functions

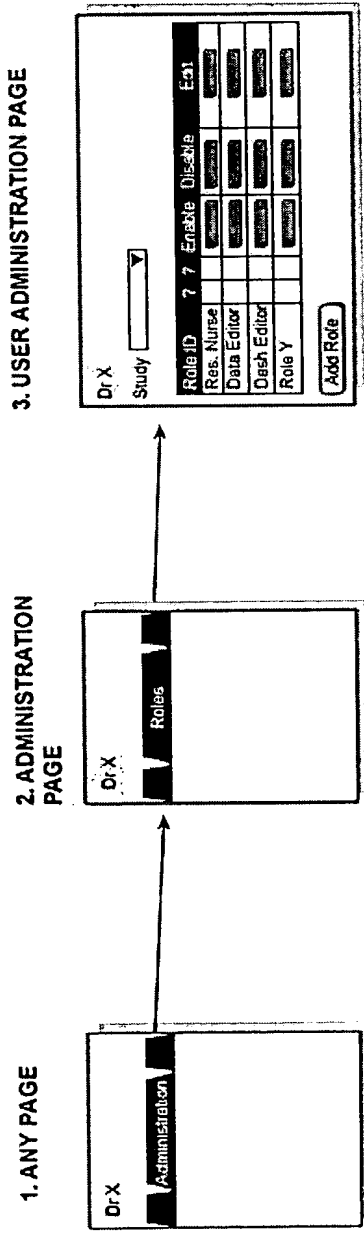
- 1. STUDY ADMIN HOME
- 2. DEPLOYED STUDIES
- 3. ENROLLMENT CRITERIA
- 4. CONFIRMATION



- User chooses close enrollment	- User selects study to close enrollment with	- System warns user that they are about to close enrollment. - User types in reason for closing enrollment	- Enrollment is closed - Enroller is notified
---------------------------------	---	---	--

Fig 13

Role Definition Function



- study administrator selects study (for which they are a study administrator) that they'd like to manipulate.
- System displays roles that are defined (if any) for the selected study. Note we have some space for "7" (TBD) characteristics.
- study administrator can add a new roles, enable/disable existing roles, and generally edit the existing roles.

- study administrator chooses "roles" tab

- study administrator chooses "administration" tab

Fig 14a

Role Definition Function (Cont.)

4. ROLE PAGE

Dr X:
For Study: XYZABC
Role: Research Nurse 3

Capabilities:
Enroll Subjects:
Disenroll Subjects:

5. CONFIRMATION PAGE

Dr X:
Changes made to study
have been committed.

- Study administrator selected Add Role or edit an existing role from previous page or

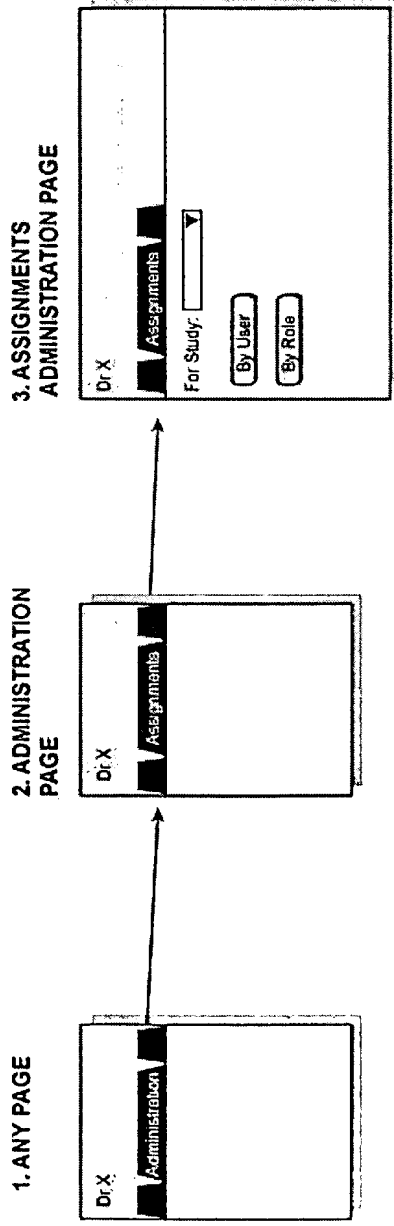
- when study administrator selects either Assign or Remove, the system refreshes the page to indicate updated information

- the *fault line* simply indicates that there are lots of capabilities and we'll need to find a nice model to reflect them.

- More discrete data-oriented capabilities like Edit Data and Review Data capabilities have a sub-table for known data sets (and the ubiquitous freeform dataset (attachment, link, or block of text)).

Fig 14b

Role Assignment Function



- study administrator chooses "administration" tab

- study administrator chooses "assignments" tab

- First the study administrator will specify the study for which they are assigning roles. The choices in the drop down are those for which they are identified as study administrators.
- They can then specify the assign roles "By User" or "By Role" -- both forms are presented as a matter of convenience.

Fig 15a

Role Assignment Function (Cont.)

4A. ROLE ASSIGNMENT BY USER PAGE OR 4B. ROLE ASSIGNMENT BY ROLE PAGE 5. CONFIRMATION PAGE

The diagram illustrates the role assignment process flow. It starts with two initial pages, 4A and 4B, which lead to a confirmation page (5).

Page 4A: ROLE ASSIGNMENT BY USER PAGE

Dr. X

Assignments

For Study: XYZABC

Apply to User: [Dropdown]

Assigned Roles [List Box] Available Roles [List Box]

Assign [Button] Remove [Button]

Submit [Button]

Page 4B: ROLE ASSIGNMENT BY ROLE PAGE

Dr. X

Assignments

For Study: XYZABC

Role: [Dropdown]

Users With Role [List Box] Users Without Roles [List Box]

Assign [Button] Remove [Button]

Submit [Button]

Page 5: CONFIRMATION PAGE

Dr. X

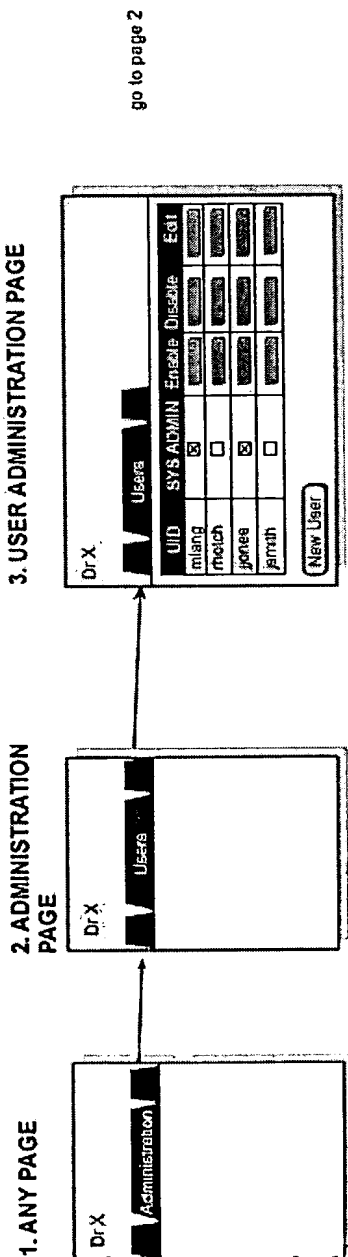
Changes to roles have been committed.

Return to Roles [Button]

- View if study administrator selected "By User"
 - study administrator can Assign/Remove roles by clicking on the "Assign" and "Remove" buttons
 - System will refresh page when user Assigns / Removes Roles
- View if study administrator selected "By Role"
 - As study administrator can assign/Remove roles by clicking on the "Assign" and "Remove" buttons (assigning users to the roles).
 - System will refresh page when user Assigns / Removes Roles
- System confirms Role assignments.

Fig 15b

User Administration Function



- User chooses "administration" tab

- User chooses "Users" tab

- System displays users
- User can:
+ add a new user,
+ enable / disable users
+ edit a user. (choosing edit will take the administrator to the next page).

Fig 16a

User Administration Function (Cont.)

4. USER PROFILE PAGE 5. CONFIRMATION PAGE

Dr X	
UID: <input type="text" value="123456"/>	Contact Data:
First Name: <input type="text" value="John"/>	<input type="text"/>
Last Name: <input type="text" value="Doe"/>	<input type="text"/>
Email: <input type="text" value="john.doe@company.com"/>	<input type="text"/>
Is System Admin: <input checked="" type="checkbox"/>	Is Study Admin: <input checked="" type="checkbox"/>
Is Registrar: <input type="checkbox"/>	Studies: <input type="text" value="Study1"/> <input type="text" value="Study2"/> <input type="text" value="Study3"/>
<input type="button" value="Submit"/>	

Dr X

Changes to UID Jasmith have been committed.

- User edits various aspects of the user's profile.
- Users click to submit changes

- System confirms the commit of changes to the user.

Fig 16b

Subject Enrollment Function

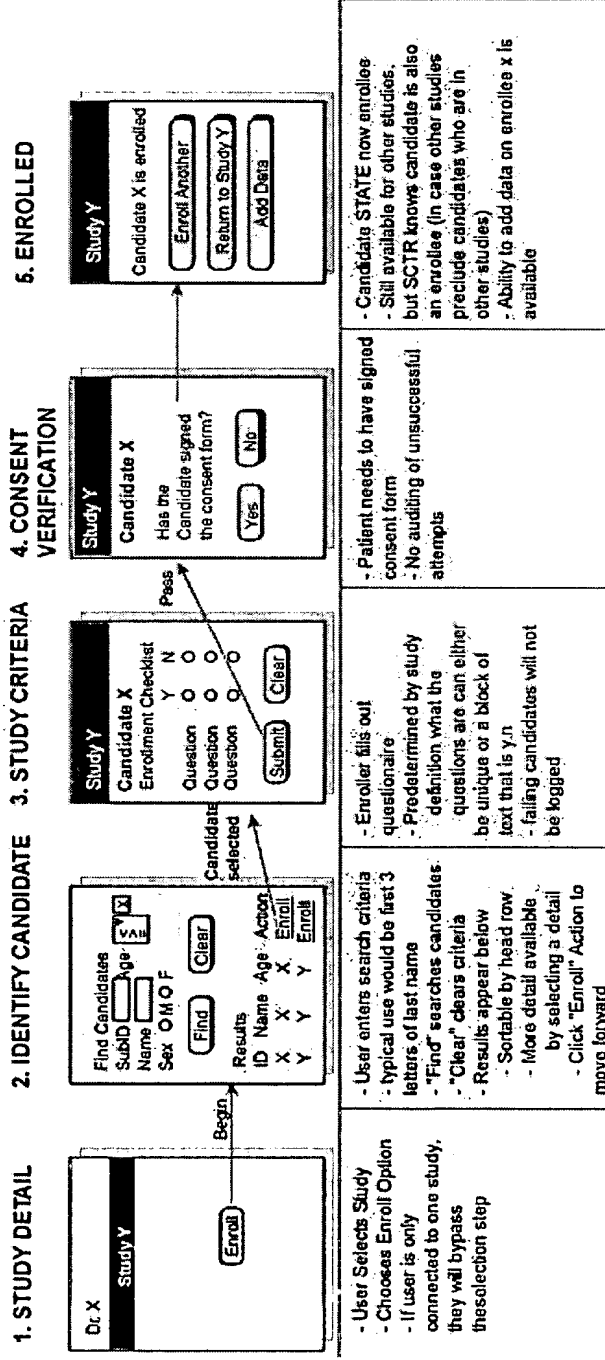


Fig 17

Add/Edit Study Data Functions

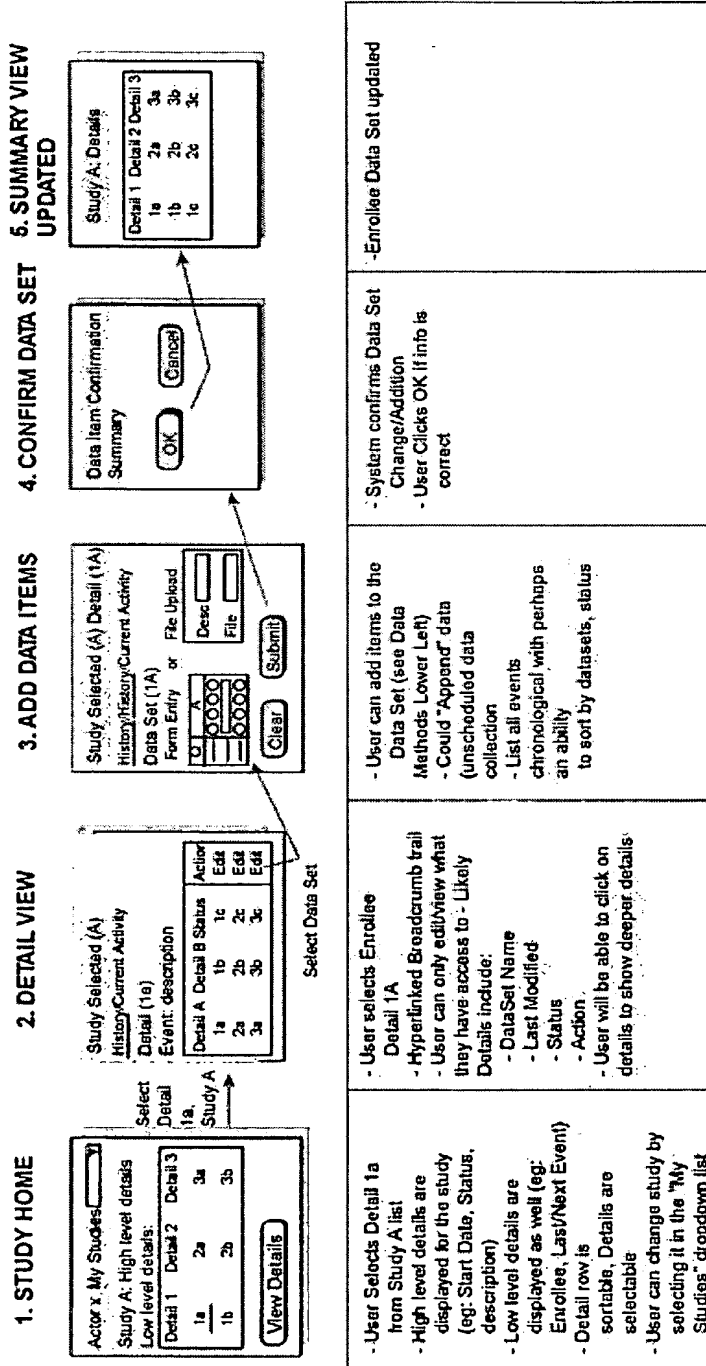


Fig 18

Add/Edit Genetics Data Functions

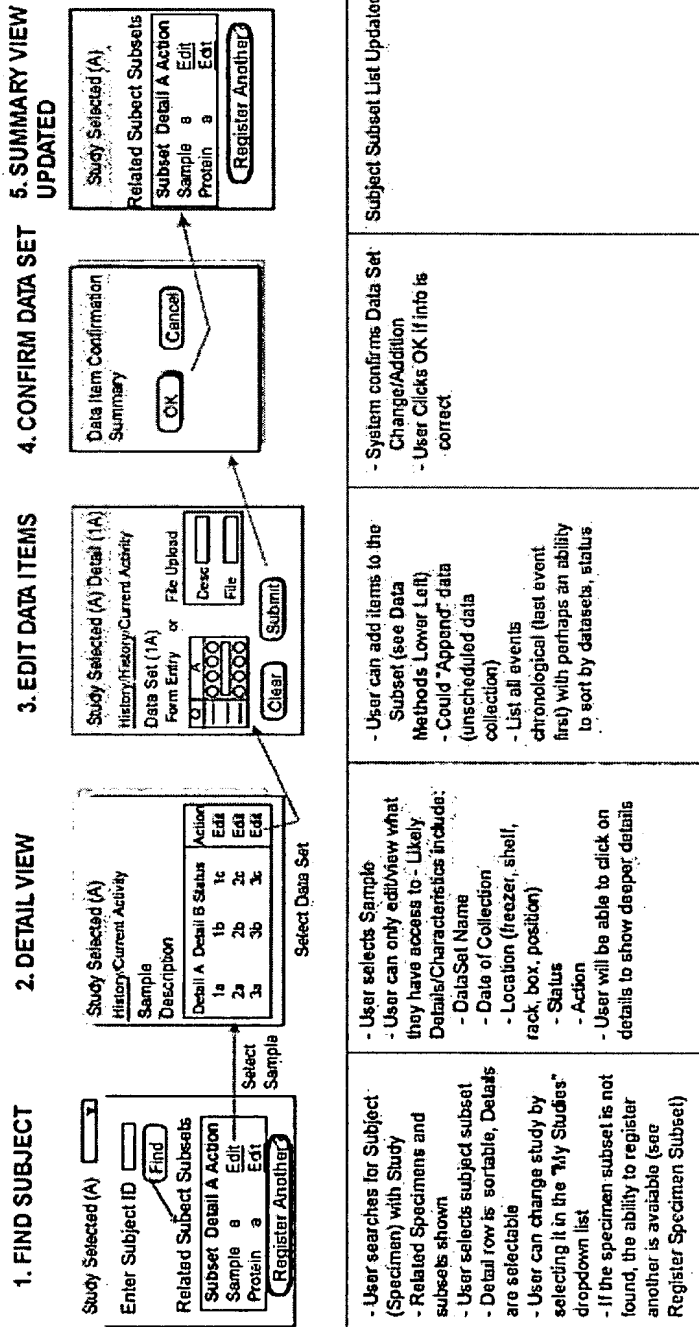


Fig 19

Approve Data Set Functions

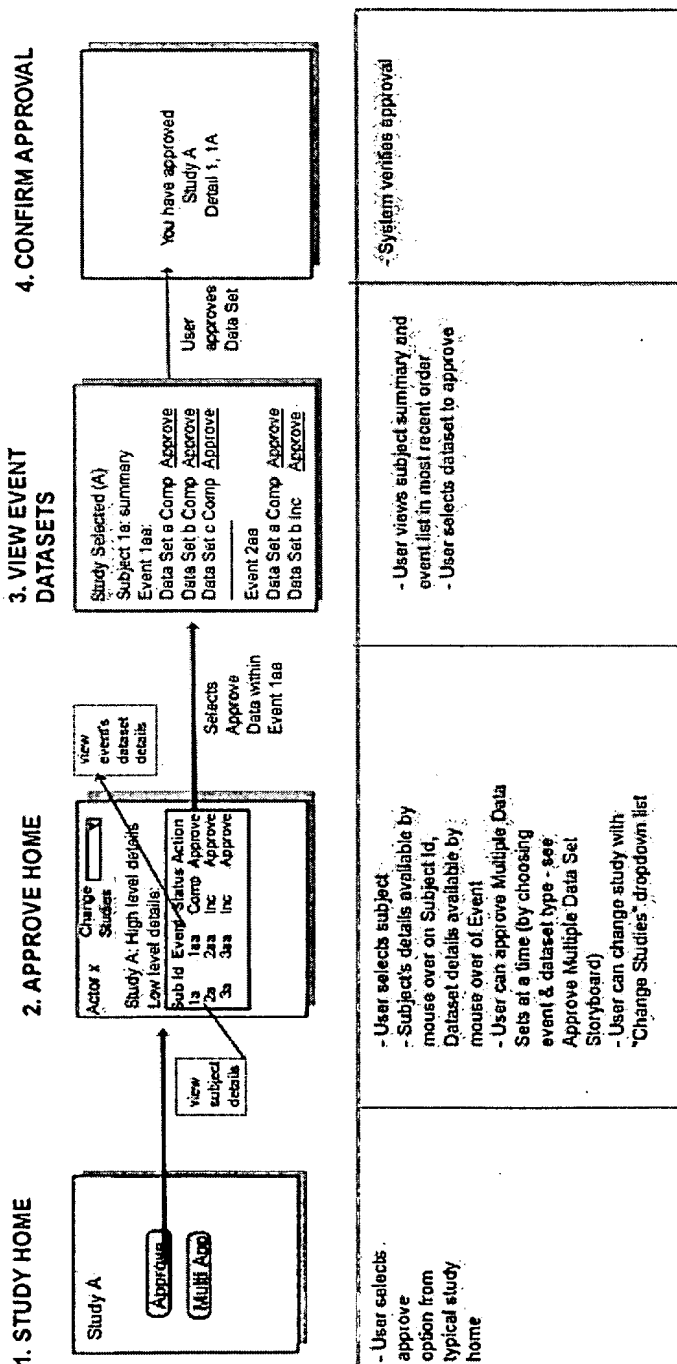
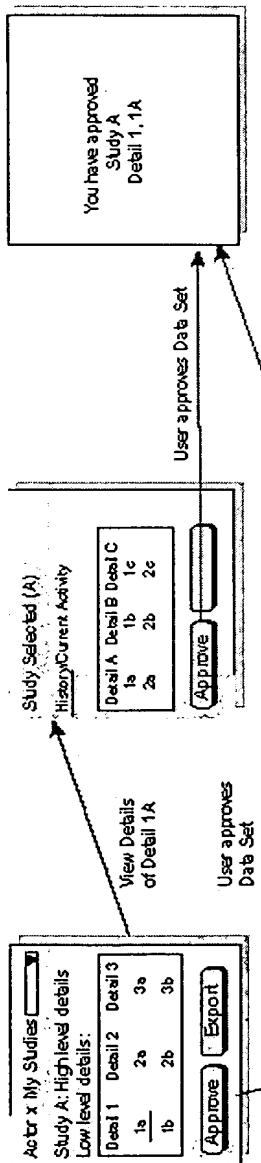


Fig 21

Approve (freeze) Data Set Functions

1. TAILORED HOME PAGE 2. VIEW DETAILS 3. CONFIRM APPROVAL



- User sees current study and the subjects enrolled in that study
 - User can approve Data Sets from this page
 - User can approve Multiple Data Sets at a time
 - User can change study by selecting it in the "My Studies" dropdown list
 - User can export data for analysis in an external tool
- User can view details of a Subject
 - User can approve data from this page
- System verifies approval

Fig 22

Reinstate Function

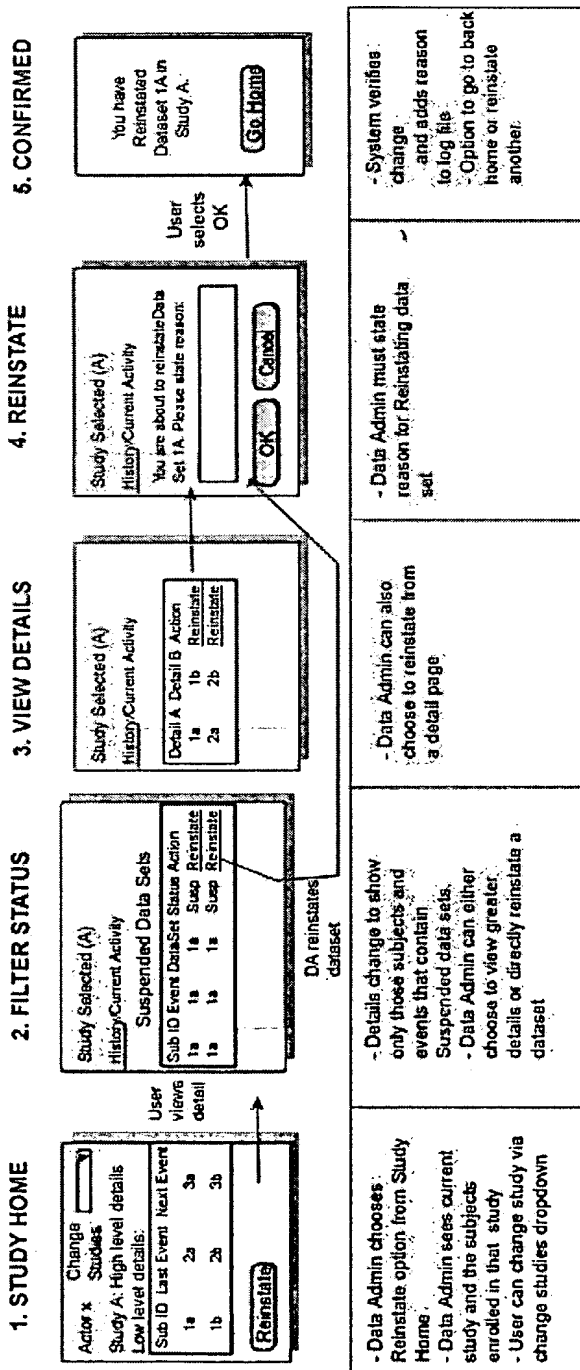


Fig 23

Back To
-- Select a Study --

SCTR Mail Message Center

SCTR Mail Home

Post Message

For:

Study:

Title:

Message:

Priority:

View Messages

To sort alerts, click on the column header that you wish to sort on.

Study:

Date	User	Title	Priority
09/30/2001	rhotchkiss	Enrollment for Basal Joint Arthritis Closed	High
09/11/2001	twright	Subject 457342 is disenrolled for study	High
07/23/2001	lariola	Subject 123442 is disenrolled for study	High
08/12/2001	rhotchkiss	Collaborator Walter Read data Set Editability Suspended	Normal
06/18/2001	rhotchkiss	Subject 123442 is disenrolled for study	Alert
09/23/2001	twright	Enrollment Closed for Basal Joint Arthritis Study	Normal
09/11/2001	lariola	Subject 123442 is enrolled into study	Low
07/23/2001	rhotchkiss	Collaborator TIGR data set editability has been Reinstated	Normal

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Fig 24

Back To
[-- Select a Study --](#)

SCTR Mail Message Center

SCTR Mail Home

Post Message

For: Priority:

Study:

Title:

Date: 09/30/2001
From: rhotchkiss
Priority: High
Title: Enrollment for Basal Joint Arthritis Closed
Message:
Enrollment for the Basal Joint Arthritis Study #445599 has been closed as of 12:30pm 09/20/2001. The maximum number of subjects have been enrolled - we have no further need for subjects at this time.

Previous Message

Next Message

Archive Message

Close Window

08/12/2001 rhotchkiss Collaborator Walter Reed data Set Editability Suspended

06/18/2001 rhotchkiss Subject 123442 is disenrolled for study

09/23/2001 twright Enrollment Closed for Basal Joint Arthritis Study

09/11/2001 lariola Subject 123442 is enrolled into study

07/23/2001 rhotchkiss Collaborator TIGR data set editability has been Reinstated

Priority

High

High

High

Normal

Alert

Normal

Low

Normal

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Fig 25

[Study Home](#)
[Manage Subjects](#)
[Reports](#)
[Administration](#)
[Register](#)

Study: 445599 Basal Joint Arthritis

[Manage Subjects Home](#)

Enrolled Subject View

Subject ID	First Name	Last Name	Sex	Age	Last Event	Status	Last Event Date	Next Event
<u>123456</u>	Mary	Smith	F	22	Initial Visit	Comp	09/11/2001	Surgery
<u>123455</u>	Brenda	Heidelberg	F	32	Initial Visit	Inc	09/11/2001	Surgery
<u>123454</u>	Helga	Rothchild	F	48	Initial Visit	Inc	09/11/2001	Surgery
<u>123453</u>	Donna	Donaldson	F	67	Surgery	App	09/19/2001	1-Mon Postop
<u>123452</u>	Flora	Dorfman	F	79	1-Mon Postop	Inc	09/11/2001	3-Mon Postop

Total number of enrollees: 27

EVENT	TBE	DATA ENTRY STATUS			
		Incomplete	Complete	Approved	Disapproved
Initial Visit	18	22	5	3	
Surgery	4	5	12	9	
1-Mon Postop	12	12	3	2	
3-Mon Postop	2	3	2	1	
3-Mon Postop	3	0	0	0	
1-Yr Postop	3	0	0	0	
2-Yr Postop	3	0	0	0	

Change Studies

View All Studies

go

Manage Subjects

Candidates

Find

Enroll

Enrolled

View

Disenroll

Events

Choose

View Scheduled

View Status

Add Unscheduled

Data Sets

Choose

Edit

Approve

Retract Approval

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Fig 26

Manage Subjects

Study: 445599 Basal Joint Arthritis

Manage Subjects: Add Unscheduled Event

Subject 123456

Add Unscheduled Event

Event Name:

Change Studies

Manage Subjects

Candidates

Find

Enroll

Enrolled

View

Disenroll

Events

Choose

View Scheduled

View Status

Add Unscheduled

Data Sets

Choose

Edit

Approve

Retract Approval

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Fig 28

Change Studies

Manage Subjects

Candidates

Find

Enroll

Enrolled

View

Disenroll

Events

Choose

View Scheduled

View Status

Add Unscheduled

Data Sets

Choose

Edit

Approve

Retract Approval

Manage Subjects

Study: 445599 Basal Joint Arthritis

Manage Subjects: Add Unscheduled Event Confirmed

Subject 123456

Add Unscheduled Event Confirmed

The Unscheduled Event Thumb Check-up has been successfully added.

Study: 445599 Basal Joint Arthritis

Subject ID: 123456

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Fig 29

Change Studies

Manage Subjects

Candidates

[Find](#)

[Enroll](#)

[View](#)

[Disenroll](#)

[Events](#)

[Choose](#)

[View Scheduled](#)

[View Status](#)

[Add Unscheduled](#)

[Data Sets](#)

[Choose](#)

[Edit](#)

[Approve](#)

[Retract Approval](#)

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Manage Subjects

Study: 445599 Basal Joint Arthritis

Manage Subjects: Subject View

Subject 123456

General Characteristics

Sex: Female
Age: 20
Race: Caucasian
Height: 6'00
Weight: 125
Eye Color: Brown

[Personal Id Info](#)

[Associated Medical Info](#)

Event List

Scheduled Events

Event	Data Status	Last Modified
Initial Study Visit	Inc	04/08/1998
Surgery	Inc	04/10/1998
1-Mon Postop	TBE	...
3-Mon Postop	Comp	04/11/1998
3-Mon Postop	Comp	04/10/1999
1-Yr Postop	Inc	04/10/2000
2-Yr Postop	Comp	04/10/2001

Unscheduled Event

Event Name	Modified
Physical Exam	04/08/1998
Surgery	04/10/1998
Thumb Check-up	10/25/2001

[Add Unscheduled Event](#)

Fig 30

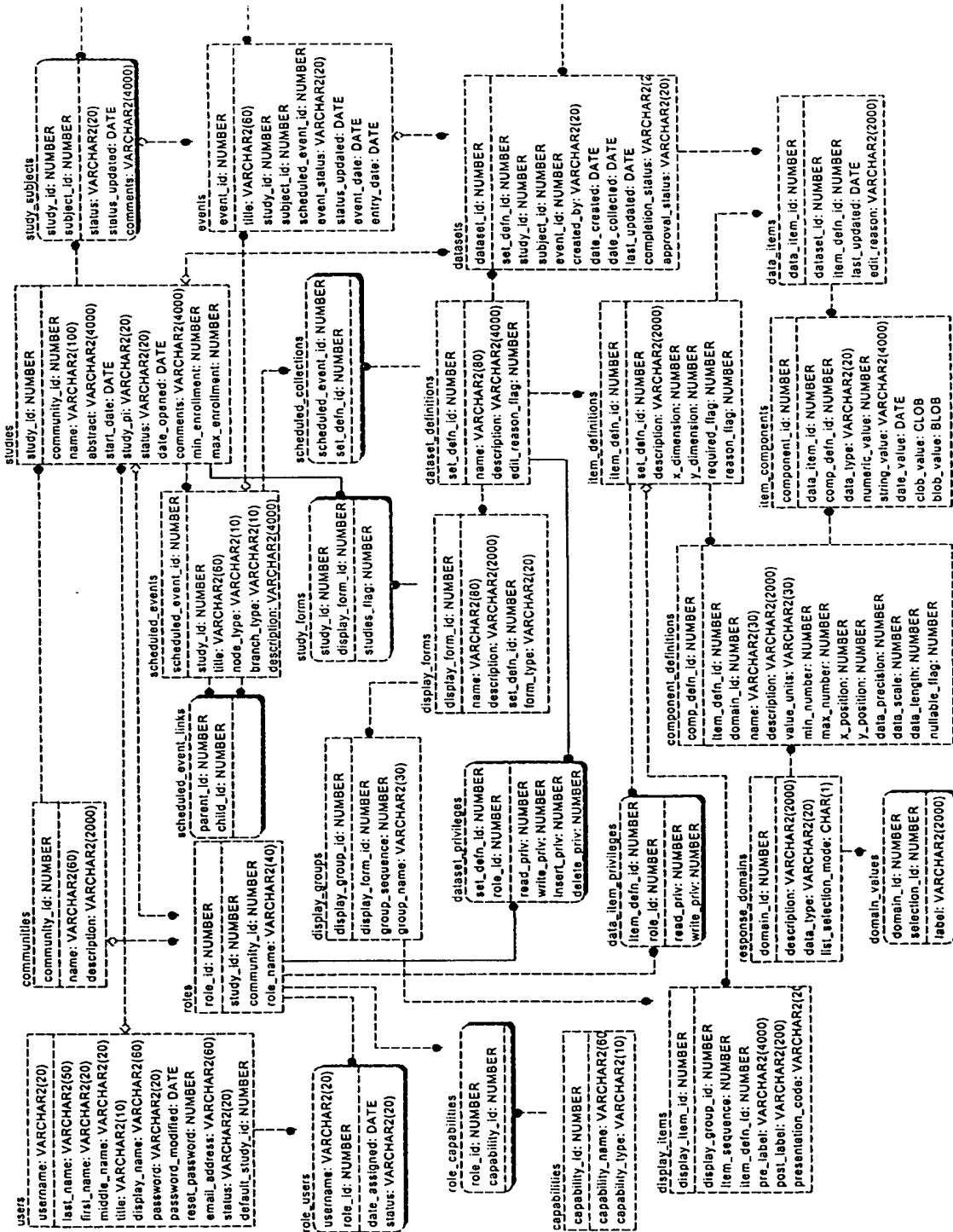


Fig 31a

